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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

U.S. PATENT & TRADEMARK OFFICE

PURDUE PHARMA PRODUCTS L.P.,
NAPP PHARMACEUTICAL GROUP LTD., and
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC.,

Plaintiffs,

v.

PADDOCK LABORATORIES, INC.,

Defendant.

C.A. No. _____

Pat. # 6,254,887
7,074,430

COMPLAINT

Plaintiffs Purdue Pharma Products L.P. and Napp Pharmaceuticals Group Ltd.,
and Ortho-McNeil-Janssen Pharmaceuticals, Inc., for their Complaint herein, aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of
the United States, Title 35, United States Code.

THE PARTIES

2. Plaintiff Purdue Pharma Products L.P. ("Purdue") is a limited partnership
organized and existing under the laws of the State of Delaware, having a place of business at One
Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue is an
owner by assignment of the patents in suit identified in paragraph 8 below.

3. Plaintiff Napp Pharmaceutical Group Ltd. ("Napp") is a private limited
company organized and existing under the laws of the United Kingdom, having a place of

business at Cambridge Science Park, Milton Road, Cambridge, CB4 0GW. Napp is an owner by assignment of the patents in suit identified in paragraph 8 below.

4. Plaintiff Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Ortho") is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 1000 Route 202 South, Raritan, New Jersey 08869. Ortho, previously Ortho-McNeil, Inc., is a licensee of the patents in suit identified in paragraph 8 below and Ortho, through its divisions, markets and distributes Ultram[®] ER in the United States.

5. Upon information and belief, defendant Paddock Laboratories, Inc. ("Paddock") is a corporation organized and existing under the laws of the State of Minnesota, having a place of business at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427-1244.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

7. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENTS IN SUIT

8. Purdue and Napp are the lawful owners of all right, title and interest in and to the following two United States patents, including all right to sue and to recover for past infringement thereof, which patents are listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) as covering Ultram[®] ER:

(a) United States Patent No. 6,254,887, entitled "CONTROLLED RELEASE TRAMADOL" ("the '887 patent"), a copy of which is attached hereto as Exhibit A,

which was duly and legally issued on July 3, 2001, naming Ronald Brown Miller, Stewart Thomas Leslie, Sandra Therese Antoinette Malkowska, Kevin John Smith, Walter Wimmer, Horst Winkler, Udo Hahn and Derek Allan Prater as the inventors.

(b) United States Patent No. 7,074,430, entitled "CONTROLLED RELEASE TRAMADOL TRAMADOL [sic] FORMULATION" ("the '430 patent"), a copy of which is attached hereto as Exhibit B, which was duly and legally issued on July 11, 2006, naming Ronald Brown Miller, Sandra Therese Antoinette Malkowska, Walter Wimmer, Udo Hahn, Stewart Thomas Leslie, Kevin John Smith, Horst Winkler and Derek Allan Prater as the inventors.

ULTRAM® ER

9. Biovail Laboratories International, SRL ("Biovail") is the holder of New Drug Application ("NDA") No. 21-692 and manufactures the controlled-release tramadol hydrochloride pain relief medication Ultram® ER.

10. Plaintiff Ortho is a licensee of the patents in suit identified in paragraph 8 above, and markets and distributes Ultram® ER in the United States.

11. In compliance with 21 U.S.C. § 355(b)(1), Biovail certified to the FDA that the '887 and '430 patent claims cover Ultram® ER.

PADDOCK'S ANDA

12. Upon information and belief, Paddock submitted Abbreviated New Drug Application No. 91-460 ("ANDA") to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, and sale of tramadol hydrochloride extended release tablets, 100 mg, 200 mg, and 300 mg

("Paddock's 100 mg, 200 mg, and 300 mg Tablets"), a generic version of Biovail's Ultram[®] ER, before the expiration of the '887 and '430 patents.

13. Upon information and belief, Paddock's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '887 and '430 patents, listed in the FDA's Orange Book as patents covering the drug Ultram[®] ER, are invalid and/or will not be infringed by the commercial manufacture, use or sale of Paddock's 100 mg, 200 mg, and 300 mg Tablets.

14. In a letter dated July 21, 2009 addressed to Purdue, Napp, and Biovail, Paddock provided "notice" with respect to its 100 mg, 200 mg, and 300 mg Tablets and the '887 and '430 patents under 21 U.S.C. § 355(j)(2)(B)(ii) ("Paddock's Notice Letter").

15. Paddock's submission of its ANDA was an act of infringement of the '887 and '430 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

16. Upon information and belief, the composition of Paddock's 100 mg, 200 mg, and 300 mg Tablets is covered by one or more claims of the '887 and '430 patents.

17. Upon information and belief, Paddock's commercial manufacture, use, sale, and/or offer for sale of its 100 mg, 200 mg, and 300 mg Tablets would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '887 and '430 patents.

18. Upon information and belief, Paddock has been aware of the existence of the '887 and '430 patents, and has no reasonable basis for believing that its 100 mg, 200 mg, and 300 mg Tablets will not infringe the '887 and '430 patents, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

19. The acts of infringement by Paddock set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

PURDUE v. PAR CASE

20. On May 5, 2007, Plaintiffs Purdue, Napp and Ortho-McNeil, Inc., along with Biovail, filed suit against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par") in the District of Delaware, Civil Action No. 07-255-KAJ, alleging infringement of the '887 patent ("the *Par* case"). On March 28, 2008, Plaintiffs Purdue, Napp and Ortho-McNeil, Inc. and Biovail filed an amended complaint against Par additionally seeking declaratory judgment of patent infringement of the '430 patent, which was not listed in the Orange Book for Ultram[®] ER at that time.¹ In response, Par denied infringement and asserted that the claims of the patents-in-suit were invalid and unenforceable due to inequitable conduct. Biovail was dismissed by consent on November 10, 2008. Ortho was dismissed for lack of standing on December 3, 2008. A five-day bench trial was held from April 16 to April 22, 2009.

21. On August 14, 2009, the District Court in *Par* issued a Judgment Order and Findings of Fact and Conclusions of Law in the *Par* case. The Court found and adjudged, *inter alia*, that:

(a) Par has literally infringed Claims 3, 13, 27, and 29 of the '887 patent, and Par's manufacture, use, and offer to sell tramadol extended release tablets in 100 mg, 200 mg, and 300 mg dosage strengths would infringe claims 5, 7, and 11 of the '430 patent;

¹ The '430 was added to the Orange Book prior to Paddock's Paragraph IV certification, which certifies against both the '887 and '430 patents listed in the Orange Book for Ultram[®] ER.

(b) Claims 3, 13, 27, and 29 of the '887 patent and claims 5, 7, and 11 of the '430 patent are invalid for obviousness; and

(c) The '887 patent and '430 patents are not unenforceable due to inequitable conduct.

22. On September 3, 2009, Plaintiffs Purdue and Napp filed a Notice of Appeal appealing the District Court's judgment of invalidity in the *Par* case to the U.S. Court of Appeals for the Federal Circuit.

23. On September 3, 2009, Plaintiff Ortho filed a Notice of Appeal appealing the District Court's order dismissing Ortho from the *Par* case to the U.S. Court of Appeals for the Federal Circuit to request reversal of the District Court's finding that Ortho lacked standing.

24. Under the Hatch-Waxman Act, Plaintiffs have 45 days after receipt of Paddock's Notice Letter to sue for infringement of the '887 and '430 patents to trigger a 30-month stay during which the FDA cannot approve Paddock's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). There can be no such stay while the patents remain invalid. The law is unclear as to whether, following a successful appeal of the District Court's decision in the *Par* case, Plaintiffs would have a right to a statutory stay of FDA approval of Paddock's ANDA if they were to file suit at that time. However, there appears to be no mechanism in the Hatch-Waxman Act by which Plaintiffs can toll the statutory requirement that suit be filed within 45 days of receipt of Paddock's Notice Letter in order for Plaintiffs to obtain such a stay, or to revive Plaintiffs' right to such a stay, if suit is not filed within 45 days.

25. Accordingly, Plaintiffs must file suit against Paddock for infringement of its 100 mg, 200 mg, and 300 mg Tablets within the 45-day timeframe provided by statute, in

order to perfect their rights to a 30-month stay prohibiting FDA approval of Paddock's ANDA if the Federal Circuit vacates or reverses the District Court's judgment in *Par*.

26. To conserve the resources of the Court and the parties, Plaintiffs will move promptly for a stay of this action against Paddock until the earlier of (a) a final adjudication of the appeal in the *Par* case or (b) a decision by the FDA to tentatively approve Paddock's product.

WHEREFORE, Plaintiffs pray for judgment:

A. Adjudging that Paddock has infringed the '887 and '430 patents, and that the commercial sale, offer for sale, and/or manufacture of Paddock's 100 mg, 200 mg, and 300 mg Tablets would infringe, induce infringement of, and/or contribute to the infringement of the '887 and '430 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Paddock's ANDA No. 91-460, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the date of expiration of the '887 and '430 patents plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Paddock, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that infringes the '887 or '430 patents;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

MASLON EDELMAN BORMAN & BRAND, LLP

s/ Michael McCarthy

Michael McCarthy (#230406)

3300 Wells Fargo Center

90 South Seventh Street

Minneapolis, MN 55402-4140

(612) 672-8347

mike.mccarthy@maslon.com

Attorneys for Plaintiffs

Purdue Pharma Products L.P.

and Napp Pharmaceutical Group Ltd.

ANTHONY OSTLUND BAER & LOUWAGIE P.A.

s/ Courtland C. Merrill

Courtland C. Merrill (#311984)

90 South 7th Street

3600 Wells Fargo Center

Minneapolis, MN 55402

(612) 349-6969

cmerrill@aoblaw.com

Attorneys for Plaintiff

Ortho-McNeil-Janssen Pharmaceuticals, Inc.

September 4, 2009

JS 44 (Rev. 12/97)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Purdue Pharma Products L.P., Napp Pharmaceutical Group Ltd., and
Ortho-McNeil-Janssen Pharmaceuticals, Inc.,

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Michael McCarthy, MASLON EDELMAN BORMAN & BRAND, LLP
3300 Wells Fargo Center, 90 South Seventh Street
Minneapolis, MN 55402-4140, (612) 672-8347

DEFENDANTS

Paddock Laboratories, Inc.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE
LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION

(Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES

(For Diversity Cases Only)

(Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | | | | | |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT

(Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance	<input type="checkbox"/> 310 Airplane	<input type="checkbox"/> 610 Agriculture	<input type="checkbox"/> 422 Appeal 28 USC 158	<input type="checkbox"/> 400 State Reapportionment
<input type="checkbox"/> 120 Marine	<input type="checkbox"/> 315 Airplane Product Liability	<input type="checkbox"/> 620 Other Food & Drug	<input type="checkbox"/> 423 Withdrawal 28 USC 157	<input type="checkbox"/> 410 Annuity
<input type="checkbox"/> 130 Miller Act	<input type="checkbox"/> 320 Assault, Libel & Slander	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881	<input type="checkbox"/> 450 Commerce	<input type="checkbox"/> 420 Banks and Banking
<input type="checkbox"/> 140 Negotiable Instrument	<input type="checkbox"/> 350 Federal Employers' Liability	<input type="checkbox"/> 630 Liquor Laws	<input type="checkbox"/> 460 Deposition	<input type="checkbox"/> 430 Bankruptcy
<input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment	<input type="checkbox"/> 360 Asbestos Personal Injury Product Liability	<input type="checkbox"/> 640 R.R. & Truck	<input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations	<input type="checkbox"/> 440 Consumer Credit
<input type="checkbox"/> 151 Medicare Act	<input type="checkbox"/> 340 Marine	<input type="checkbox"/> 640 Airline Regs.	<input type="checkbox"/> 480 Trademark	<input type="checkbox"/> 490 CableSat TV
<input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans)	<input type="checkbox"/> 345 Marine Product Liability	<input type="checkbox"/> 660 Occupational Safety/Health	<input type="checkbox"/> 490 Selective Service	<input type="checkbox"/> 500 Securities/Commodities/Exchange
<input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits	<input type="checkbox"/> 350 Motor Vehicle	<input type="checkbox"/> 690 Other	<input type="checkbox"/> 510 Fair Labor Standards Act	<input type="checkbox"/> 520 Customer Challenge 12 USC 3410
<input type="checkbox"/> 160 Stockholders' Suits	<input type="checkbox"/> 355 Motor Vehicle Product Liability	<input type="checkbox"/> 700 Labor/Mgmt. Relations	<input type="checkbox"/> 530 Black Lung (923)	<input type="checkbox"/> 530 Agricultural Acts
<input type="checkbox"/> 190 Other Contract	<input type="checkbox"/> 360 Other Personal Injury	<input type="checkbox"/> 750 Labor/Mgmt. Reporting & Disclosure Act	<input type="checkbox"/> 540 SSND Title XVI	<input type="checkbox"/> 540 Other Statutory Actions
<input type="checkbox"/> 195 Contract Product Liability	<input type="checkbox"/> 370 Other Fraud	<input type="checkbox"/> 740 Railway Labor Act	<input type="checkbox"/> 565 RSI (405(g))	<input type="checkbox"/> 550 Agricultural Acts
<input type="checkbox"/> 196 Franchise	<input type="checkbox"/> 371 Truth in Lending	<input type="checkbox"/> 790 Other Labor Litigation	<input type="checkbox"/> 570 Taxes (U.S. Plaintiff or Defendant)	<input type="checkbox"/> 560 Economic Stabilization Act
<input type="checkbox"/> 210 Land Condemnation	<input type="checkbox"/> 380 Other Personal Property Damage	<input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="checkbox"/> 580 Freedom of Information Act	<input type="checkbox"/> 570 Appeal of Fee Determination Under Equal Access to Justice
<input type="checkbox"/> 220 Foreclosure	<input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 402 Naturalization Application	<input type="checkbox"/> 590 Environmental Matters	<input type="checkbox"/> 580 Energy Allocation Act
<input type="checkbox"/> 230 Rent Lease & Ejectment	<input type="checkbox"/> 400 Civil Rights	<input type="checkbox"/> 463 Habeas Corpus - Alien Detainee	<input type="checkbox"/> 590 Freedom of Information Act	<input type="checkbox"/> 590 Freedom of Information Act
<input type="checkbox"/> 240 Torts to Land	<input type="checkbox"/> 440 Amer. w/Disabilities - Other	<input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 600 Appeal of Fee Determination Under Equal Access to Justice	<input type="checkbox"/> 600 Appeal of Fee Determination Under Equal Access to Justice
<input type="checkbox"/> 245 Tort Product Liability	<input type="checkbox"/> 440 Other Civil Rights		<input type="checkbox"/> 610 Appeal of Fee Determination Under Equal Access to Justice	<input type="checkbox"/> 610 Appeal of Fee Determination Under Equal Access to Justice
<input type="checkbox"/> 290 All Other Real Property			<input type="checkbox"/> 620 Appeal of Fee Determination Under Equal Access to Justice	<input type="checkbox"/> 620 Appeal of Fee Determination Under Equal Access to Justice

V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

35 U.S.C. § 271

Brief description of cause:

Patent Infringement

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Jordan (D. Del.)

DOCKET NUMBER

07-255 07-414
07-666 08-519

DATE: September 4, 2009

SIGNATURE OF ATTORNEY OF RECORD
s/ Michael C. McCarthy

08-827

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RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____